About the Authors

Brenda Davy, PhD, RDN, is a Professor in the Department of Human Nutrition, Foods and Exercise at Virginia Tech. She conducts research investigating the role of diet and physical activity behaviors in the prevention and treatment of obesity and related comorbidities, beverage consumption and weight management, and dietary assessment methodologies. To date, Davy has published more than 100 peer-reviewed journal articles. At Virginia Tech, she directs the Laboratory for Eating Behaviors and Weight Management and teaches graduate and undergraduate courses in health assessment and research methods. Davy currently serves on the Board of Editors for the Journal of the Academy of Nutrition and Dietetics.

Kim Stote, PhD, MPH, RDN, is an Associate Dean for Health Professions at the State University of New York, Empire State College. She earned a doctorate of nutrition science from Syracuse University, a master of public health (MPH) from the School of Public Health at the University of South Florida, and a postdoctoral fellowship at the Food Components and Health Laboratory, Beltsville Human Nutrition Research Center, Agricultural Research Service, United States Department of Agriculture. Stote teaches courses in research methodology to undergraduate and Master of Science, Dietetic Internship students. She has published and presented widely in her field to include over 50 peer-reviewed published abstracts and scientific journal articles. In addition, she is a two-time recipient of a Fulbright Scholar award as Research Chair of Nutrisciences and Health at the University of Prince Edward Island, Prince Edward Island, Canada.

Acknowledgement

Special thanks to Kathy Stanczyk, PhD, RD, LD, Didactic Program Director at Murray State University for several assignments for the manual.

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Introduction

This Instructor’s Resource Manual was designed to complement the fourth edition of Research: Successful Approaches in Nutrition and Dietetics, which may be used as an upper-level undergraduate or graduate level dietetics research methods course textbook. The textbook and manual are organized into 30 chapters that span 10 major sections. This manual was developed by dietetics educators and researchers to assist course instructors with content delivery and assessment.

RESEARCH COMPETENCIES AND PERFORMANCE INDICATORS

This manual may be used by dietetics program faculty and course instructors to develop competency-based course plans for nutrition and dietetics research courses. This manual includes a variety of learning activities that may be used to conduct both formative evaluations (ie, those that promote and evaluate student learning) and summative evaluations (ie, those that evaluate student learning following completion of a chapter/section). These evaluations may be used to assess student achievement on required dietetics education competencies developed by the accrediting agency for dietetics programs, Accreditation Council for Education in Nutrition and Dietetics (ACEND).

ACEND competencies (2017) most closely related to research for Future Education Model Bachelor’s and Graduate Degree programs are listed in Appendix A and Appendix B, respectively. Learning activities that may be used to evaluate student achievement of competencies are provided. Multiple learning activities are listed for most competencies, which will allow instructors to select activities most appropriate for their course. This manual may be used in upper-level undergraduate or graduate-level nutrition research courses; examples of both graduate- and undergraduate-level learning activities are provided.

LEARNING ACTIVITIES

Each chapter in this manual includes chapter learning objectives, five to seven quiz questions (with correct responses), and two to three class discussion topics.

Instructors could use the chapter quizzes in two ways. First, quizzes could be used as a readiness assessment test (RAT) at the beginning of a class period to assess student knowledge and comprehension of the reading material after students have completed assigned chapter readings prior to attending class. In this way, the RAT can be used as an in-class learning activity, during which RAT questions and answers are discussed (ie, formative assessment). This is consistent with a “flipped classroom” learning approach. Alternatively, the quizzes could be used to assess student knowledge following completion of each chapter (as a summative evaluation). Each section in this manual includes a student assignment, which may be used as a more extensive summative evaluation of student knowledge and application.
POWERPOINT SLIDES

Slides are provided for each book chapter. Each slide set follows the sequence of content delivered in each chapter and concludes with a summary of key points. Slides may be customized to fit course needs.

HANDOUTS

Handouts with the quiz questions and section assignments are included in separate Microsoft Word documents. These files can be customized to fit the needs of the course.

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CHAPTER 7

Analytic Nutrition Epidemiology

LEARNING OBJECTIVES

1. Define analytic nutrition epidemiology.
2. Describe measures of association between a diet exposure and an outcome of interest.
3. Describe study designs for the association between a diet exposure and an outcome of interest.
4. Explain factors that may influence study results.
5. Explain potential inconsistencies between study results.

Quiz Questions and Answers

1. A cross-sectional study investigates vitamin E intake and risk of arthritis in older adults. This type of study is (circle one) observational/experimental. A second study is done in which older adults with arthritis are randomly assigned to either a daily vitamin E supplement condition or placebo supplement condition for 8 weeks. This type of study is (circle one) observational/experimental.

   observational
   experimental

2. The _____ is the proportion of participants with a disease or condition who have been exposed compared with the proportion not exposed.

   a. odds ratio
   b. attributable risk
   c. etiologic fraction
   d. relative risk

3. In epidemiological studies, the Bradford Hill criteria may be used to infer causation, since it may not be ethical or possible to perform a study to test for causation (e.g., something that may cause cancer). If a variety of studies with different designs have reported similar associations between an exposure (e.g., diet) and a disease outcome, this meets the criteria of (circle one) strength/consistency. If biological evidence from a variety of experiments (e.g., animal models, human clinical studies) suggest that an exposure is linked to a disease outcome, this meets the criteria of (circle one) biological plausibility/association specificity.

   consistency
   biological plausibility
CHAPTER 7

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Answers will be visible to dietetics educators who download the Instructor’s Resource Kit

2. The _____ is the proportion of participants with a disease or condition who have been exposed compared with the proportion not exposed.

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Answers will be visible to dietetics educators who download the Instructor’s Resource Kit
4. Briefly describe what is meant by a retrospective and prospective cohort study.

5. Case-control studies are well-suited for studies for which of the following (select two)?
   a. Of rare disorders
   b. Of common disorders
   c. Where the time between exposure and outcome is short
   d. Where the time between exposure and outcome is long

Class Discussion Topics

Describe what is meant by these types of potential methodologic sources of bias in research and discuss study design approaches that can be used to minimize bias: selection bias, recall bias, and measurement bias. What are other potential sources of bias?

Discuss reverse causation and confounding, which can represent major limitations in epidemiological research. What are some examples where these problems could lead to inaccurate conclusions about the influence of dietary factors on health outcomes in cross-sectional research studies?

A variety of study designs are utilized in nutrition and health-related research. As an in-class activity, construct a table presenting the pros and cons of these research designs: cross-sectional, cohort, and randomized controlled trials.
4. Briefly describe what is meant by a retrospective and prospective cohort study.

Retrospective studies examine exposures looking backward in time whereas prospective studies examine exposures looking forward in time.

5. Case-control studies are well-suited for studies for which of the following (select two)?

a. Of rare disorders
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4. Explain factors that may influence study results.
5. Explain potential inconsistencies between study results.

Review chapter objectives.
Define analytic nutrition epidemiology.

- Nutrition epidemiology explains the described occurrence of disease or disease-related phenomena in relation to diet and nutrition.
GOALS OF ANALYTIC EPIDEMIOLOGY

- Establish association
  - define it
  - measures
  - study designs
- Establish causation
  - define it
  - criteria
  - study designs
## Box 7.1 Measures of Association

<table>
<thead>
<tr>
<th>Measure</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative risk</strong></td>
<td>( \frac{\text{Cumulative incidence in the exposed}}{\text{Cumulative incidence in the unexposed}} )</td>
</tr>
<tr>
<td><strong>Odds ratio</strong></td>
<td>( \frac{\text{Exposed cases} \times \text{Unexposed controls}}{\text{Unexposed cases} \times \text{Exposed controls}} )</td>
</tr>
<tr>
<td><strong>Etiological fraction</strong></td>
<td>( \frac{\text{Exposed cases} - \text{Unexposed cases}}{\text{Exposed cases}} )</td>
</tr>
<tr>
<td><strong>Attributable risk</strong></td>
<td>Cumulative incidence in the exposed – Cumulative incidence in the unexposed</td>
</tr>
<tr>
<td><strong>Population attributable risk</strong></td>
<td>Cumulative incidence in the population – Cumulative incidence in the unexposed</td>
</tr>
</tbody>
</table>

*Discuss Box 7.1: Measures of Association.*
Box 7.2  Bradford Hill Criteria for Causation

| Association’s consistency$^a$ |
| Association’s strength$^a$ |
| Association’s specificity$^a$ |
| Association’s temporality |
| Biological gradient (dose/response)$^a$ |
| Biological plausibility$^a$ |
| Coherence |
| Experimental evidence |

$^a$ Reduced criteria for diet and nutrition studies agreed upon by Potischman and Weed$^{11}$ and the Committee on Diet and Health, Food and Nutrition Board, National Research Council.$^{12}$

Discuss Box 7.2: Bradford Hill Criteria for Causation.
Figure 7.1  Relative risk

Discuss Figure 7.1: Relative risk.
## CONCEPTS IN ANALYTIC NUTRITION EPIDEMIOLOGIC STUDIES

- Analytic nutrition epidemiology question
- Diet or nutrient as an exposure
- Choice of nutrition exposure variable(s)
- Problems resulting from poor exposure measurements
- Potential for other biases
- Potential for confounding
- Potential for effect modification
- Multivariate relationship of diet and disease
Figure 7.2  Comparison of predictive values

Discuss Figure 7.2: Comparison of predictive values.
ANALYTIC EPIDEMIOLOGIC STUDY DESIGNS

- Observational study designs for examining associations
  - Cross-sectional studies
  - Cohort studies
  - Case-control studies

Introduction

There are three observational study designs for examining associations.

- Cross-sectional studies, also called prevalence studies or surveys, are those where participants are measured at approximately the same point in time.
- Cohort studies track health information of participants over a period of time. They focus on disease development and survival or mortality and allow the study of the natural history of disease.
- Popular among epidemiologists examining diet and nutrition questions, the case-control design, examines cases and controls for risk factor or prior exposure differences.
Table 7.1  Advantages and Disadvantages of Observational Study Designs

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cross-Sectional</th>
<th>Case-Control</th>
<th>Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relatively cost efficient</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Relatively short duration</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Able to determine time sequence of events</td>
<td>No</td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td>Small sample size</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Differential measurement bias</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Yields prevalence</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Yields incidence, relative risk</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Useful to study rare outcomes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>More bias/confounding because there are two samples</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Only one outcome can be studied</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hypothesis generating</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Useful to study many exposures/outcomes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Avoids dropouts from long-term followup</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Discuss Table 7.1: Advantages and Disadvantages of Observational Study Designs.
ANALYTIC EPIDEMIOLOGIC STUDY DESIGNS

- Etiologic study designs
  - RCT
  - Group-randomized trials
  - Multicenter RCTs
INCONSISTENT STUDY FINDINGS AMONG NUTRITION STUDIES

- Systematic error (bias) and random error (variability)
- Differences in study methodology

Explain factors that may influence study results. Explain potential inconsistencies between study results.

- Results from nutrition studies may be inconsistent for a variety of reasons, including systematic error (bias) or random error (variability) of exposure or outcome measurement(s).
- Another reason for inconsistent findings may be the differences between studies in their conduct, most importantly, study design, population, and methods of data collection.
Recap & Discussion
1. Circle the best choice in the passage below.

A cross-sectional study investigates vitamin E intake and risk of arthritis in older adults. This type of study is [ **Observational** | **Experimental** ].

A second study is done in which older adults with arthritis are randomly assigned to either a daily vitamin E supplement condition or placebo supplement condition for 8 weeks. This type of study is [ **Observational** | **Experimental** ].

2. The _____ is the proportion of participants with a disease or condition who have been exposed compared with the proportion not exposed.

   a. odds ratio
   b. attributable risk
   c. etiologic fraction
   d. relative risk

3. Circle the best choice in the passage below.

In epidemiological studies, the Bradford Hill criteria may be used to infer causation, since it may not be ethical or possible to perform a study to test for causation (e.g., something that may cause cancer). If a variety of studies with different designs have reported similar associations between an exposure (e.g., diet) and a disease outcome, this meets the criteria of [ **Strength | Consistency** ].

If biological evidence from a variety of experiments (e.g., animal models or human clinical studies) suggest that an exposure is linked to a disease outcome, this meets the criteria of [ **Biolgical Plausibility | Association** ].
CHAPTER 7

Analytic Nutrition Epidemiology

1. Circle the **best** choice in the passage below.

   A cross-sectional study investigates vitamin E intake and risk of arthritis in older adults. This type of study is [**OBSERVATIONAL** | **EXPERIMENTAL**]. A second study is done in which older adults with arthritis are randomly assigned to either a daily vitamin E supplement condition or placebo supplement condition for 8 weeks. This type of study is [**OBSERVATIONAL** | **EXPERIMENTAL**].

2. The _____ is the proportion of participants with a disease or condition who have been exposed compared with the proportion not exposed.
   
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3. Circle the **best** choice in the passage below.

   In epidemiological studies, the Bradford Hill criteria may be used to infer causation, since it may not be ethical or possible to perform a study to test for causation (eg, something that may cause cancer). If a variety of studies with different designs have reported similar associations between an exposure (eg, diet) and a disease outcome, this meets the criteria of [**STRENGTH** | **CONSISTENCY**]. If biological evidence from a variety of experiments (eg, animal models or human clinical studies) suggest that an exposure is linked to a disease outcome, this meets the criteria of [**BIOLOGICAL PLAUSIBILITY** | **ASSOCIATION**].
4. Briefly describe what is meant by a retrospective and prospective cohort study.

5. Case-control studies are well suited for studies for which of the following (select two)?
   a. Of rare disorders
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   c. Where the time between exposure and outcome is short
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